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July 27, 2004

Division of Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2004D-0193

To Whom It May Concern:

Listed below are our comments regarding the document *Eligibility Determination of Human Cells, Tissue, and Cellular and Tissue-Based Products.*

Thank you for your consideration of our comments in formulating the final rule.

Sincerely,

S. Breanndan Moore

S. Breanndan Moore, M.D.
Division Chair, Transfusion Medicine
Mayo Clinic Rochester

cc: Jeffrey Winters, M.D.
Dennis Gastineau, M.D.
Mary Foss
Sheryl Tran

2004D-0193

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Section		Comment
II (F)	What records must accompany the HCT/P after the donor eligibility determination has been completed? The summary of records must include: • a statement that the communicable disease testing was performed by a laboratory or laboratories: (1) certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493; or (2) meeting equivalent requirements, as determined by the Centers for Medicare and Medicaid Services (CMS)	We disagree with the requirement to include a statement of certification on the summary report. The testing requirements clearly state that a CLIA certified (or equivalent) laboratory must perform testing, thus the results of tests performed imply that a certified laboratory performed the tests. We feel it is more appropriate to assure that testing records (including testing facility identification) are readily available upon request at the facility determining donor eligibility.
III (E.10)	What risk factors do I look for when screening a donor? 10. Persons who within 12 months of donation have undergone tattooing, ear piercing, or body piercing in which shared instruments are known to have been used	Was acupuncture intentionally removed from this requirement or was this an oversight?
III (F.3)	Syphilis infection • persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months. FDA recommends that, after 12 months, the donor may be re-entered after presenting evidence of successful treatment for syphilis	Is this paragraph intended to address only syphilis or both syphilis and gonorrhea? The header and the last sentence refer only to syphilis however the first sentence refers to both syphilis and gonorrhea. If gonorrhea is included in this section please add to the header and define acceptance criteria.
III (G.4)	What physical evidence do I look for? 4. Physical evidence of recent tattooing, ear piercing, or body piercing	Define "recent" or remove from this sentence.

Section		Comment
VII (C)	Any HCT/P made available under the provisions from an otherwise ineligible donor must be labeled prominently with the Biohazard legend and with the statement … in the case of reactive test results, "WARNING: Reactive test results for (name of disease agent or disease)	We agree that products must be clearly labeled biohazard, however the identification of the disease or disease agent is unnecessary and inappropriate in relation to donor confidentiality. Who are you trying to inform with this labeling requirement? The intended recipient will have been informed of the potential risks at the time the reactive test result is reported to the physician responsible for transplantation. Labeling the product with the disease or disease agent will not improve the safety of the product and may only unintentional inform others (i.e., family members, friends, etc.) of the reactive results thus breaching donor confidentiality. If the intent is to notify the recipient when the product is infused, transferred, etc. and prevent the product use, in certain situations, such as hematopoietic progenitor cell products, it is far to late because the patient has undergone myeloablative conditioning therapy and without infusion of the product, the patient will die. We encourage you to eliminate the requirement to label products with the name of the disease agent or disease for reactive results.

During review of this document we noted some inconsistencies between the *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)* documents and the latest blood donor criteria document entitled *Acceptable Full-Length Donor History Questionnaire*. Please consider coordinating these two requirements preferably using the HCT/P requirements for all donors.

Blood Donor Questionnaire	HCT/Ps Document
Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor? If yes, defer donor indefinitely.	III. E. 2 - persons who have injected drugs for non-medical reason in the preceding five years, including intravenous, intramuscular, or subcutaneous
From 1977 to the present have you received money, drugs, or other payment for sex?	III. E. 4 - persons who have engaged in sex in exchange for money or drugs in the preceding five years
Have you ever had hepatitis? If yes, determine how old donor was. If before 11th birthday-Accept; if after 11th birthday-Defer.	III. E. 11 - persons who have had a past diagnosis of clinical, symptomatic viral hepatitis after age 11, unless evidence from the time of illness documents that the hepatitis was identified as hepatitis A